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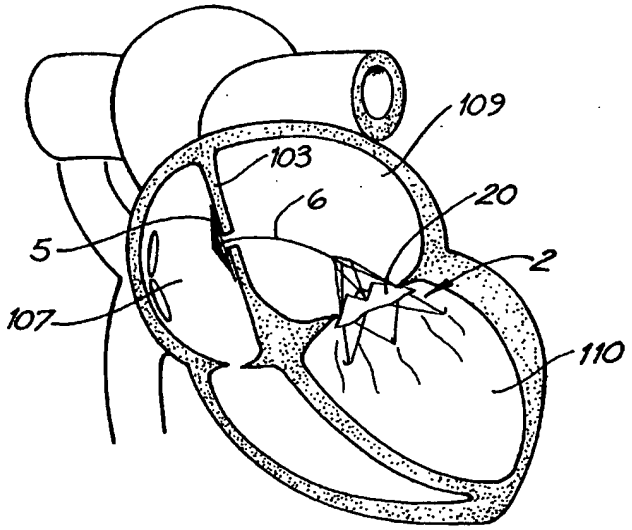
(54) Title: PERCUTANEOUS HEART VALVE PROSTHESIS



(57) Abstract: A percutaneous heart valve prosthesis (1) has a valve body (2) with a passage (9) extending between the first and second ends (7, 8) of the valve body (2). The valve body (2) is collapsible about a longitudinal axis (10) of the passage (9) for delivery of the valve body (2) via a catheter (18). One or more flexible valve leaflets (3, 4) are secured to the valve body (2) and extend across the passage (9) for blocking bloodflow in one direction through the passage (9). An anchor device (5), which is also collapsible for delivery via catheter (18), is secured to the valve body (2) by way of an anchor line (6). A failed or failing mitral heart valve (101) is treated by percutaneously locating the valve body (2) in the mitral valve orifice (102) with the anchor device (5) located in the right atrium (107) and engaging the inter-atrial septum (103), such that the taught anchor line (6) acts to secure the valve body (2) within the mitral valve orifice (102).

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PERCUTANEOUS HEART VALVE PROSTHESIS

Field of the Invention

The present invention relates to a percutaneous heart valve prosthesis, and particularly relates to, but is not limited to, a percutaneous mitral valve prosthesis.

Background of the Invention

Heart valve regurgitation is a condition whereby the heart valve does not seal completely as a result of disease or injury, and may have fatal consequences.

Malfunctioning heart valves have typically been replaced with mechanical or biologic heart valve prostheses using highly invasive open-heart surgery techniques. Whilst there has been some success in developing replacement aortic valve prostheses for delivery via percutaneous catheter-based methods, these techniques have not been particularly successful when applied to mitral valve prostheses.

Mitral valve replacement is firstly made difficult as a result of the anatomy of the mitral valve, and particularly that of the mitral valve annulus in which the mitral valve leaflets are located. The mitral valve annulus is typically very distorted, and of unpredictable and non-uniform geometries, as compared to the relatively uniform aortic valve annulus. This unpredictable anatomy makes it difficult to design a pre-constructed mitral valve prosthesis that would fit the mitral valve annulus in a satisfactory manner for safe, stable and meticulous deployment.

Further, unlike the aortic valve annulus which is entirely surrounded by muscular tissue, the mitral valve annulus is bounded by muscular tissue on the outer wall only, with the inner side of the mitral valve annulus being bounded by a thin vessel wall which separates the mitral valve annulus and the aortic outflow tract. As a result, the mitral valve annulus cannot be subjected to any significant radial forces, as would be typical with an expanding stent type of valve prosthesis, as such radial forces would tend to collapse the aortic outflow tract, resulting in circulatory collapse with likely fatal consequences. As a result of these difficulties, firm anchoring of a deployed mitral valve prosthesis is currently not readily obtainable.

Mitral valve replacement techniques have also generally advocated removal of the native valve prior to location of the replacement mitral valve prosthesis. This is a technically extremely challenging task associated with the potentially fatal complication

of profound mitral regurgitation that may not be adequately addressed by the subsequent valve replacement. The lack of an effective mitral valve may lead to overwhelming hemodynamic instability that may not be tolerated by the already compromised left ventricle and overwhelming pulmonary edema may rapidly result.

Object of the Invention

It is the object of the present invention to overcome or substantially ameliorate at least one of the above disadvantages.

Summary of the Invention

There is disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

an anchor device, said anchor device being collapsible for delivery via catheter; and

an anchor line secured to and extending between said valve body and said anchor device.

The anchor device may comprise a collapsible anchor frame formed of elongate elastic anchor frame elements. The anchor frame may be collapsible from a stable substantially flat plate-like configuration to an unstable elongate configuration for location within a catheter. The anchor frame elements may each be formed of a superelastic shape memory material.

The valve body may comprise a collapsible valve body frame formed of elongate elastic valve body elements. The valve body frame elements may each be formed of a superelastic shape memory material.

The valve body typically tapers toward said valve body first end. The anchor line is then usually secured to said valve body first end.

The valve body frame may comprise at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and

oblique-angled vertices located between said valve body first and second ends. Each valve body sub-frame member may have the general form of a rhombus.

The valve body sub-frame members may be joined at respective said oblique-angled vertices.

Each sub-frame member may further comprise a collapsible diagonal element extending between said oblique-angled vertices. The one or more valve elements is/are generally secured to the diagonal elements.

The valve body frame may alternatively be in the general form of a collapsible cylindrical ring.

The prosthesis may further comprise a plurality of prongs spaced about a periphery of said valve body for engaging the native wall of a valve orifice in use.

The prosthesis may still further comprise a flexible skirt extending about a periphery of said valve body for blocking blood flow in said one direction between said valve body and the native wall of a valve orifice in use. Said flexible skirt may be formed of biological material, typically pericardial material.

The prosthesis is typically a mitral valve prosthesis.

There is further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end, said anchor device being in a collapsed state and located between said valve body and said catheter second end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said anchor device and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined above in said catheter with said valve body and said anchor device in a collapsed state, said valve body being located between said anchor device and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve;

withdrawing said catheter first end through said puncture and into said right atrium;

advancing said anchor device through said catheter until said anchor device is released from said catheter first end, thereby expanding said anchor device from said collapsed state;

engaging said anchor device with said inter-atrial septum about said puncture; and

withdrawing said catheter from the patient.

There is yet further disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

wherein said valve body tapers toward said valve body first end, said valve body first end being sized to pass through a valve orifice associated with a heart valve to be replaced, said valve body second end being sized so as not to pass through the valve orifice.

The valve body may comprise a collapsible valve body frame formed of elongate elastic valve body elements. The valve body frame elements may each be formed of a superelastic shape memory material.

The valve body frame may comprise at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and oblique-angled vertices located between said valve body first and second ends. Each valve body sub-frame member may have the general form of a rhombus.

The valve body sub-frame members may be joined at respective said oblique-angled vertices.

Each sub-frame member may further comprise a collapsible diagonal element extending between said oblique-angled vertices. The one or more valve elements is/are generally secured to said diagonal elements.

The prosthesis is typically a mitral valve prosthesis.

There is yet further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing heart valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined above in said catheter with said valve body in a collapsed state and said valve body second end located between said valve body first end and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, wedging said valve body in the orifice of the native mitral valve; and

withdrawing said catheter from the patient.

There is still further disclosed herein a percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body

second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

a flexible skirt extending about a periphery of said valve body for blocking bloodflow in said one direction between said valve body and the native wall of a valve orifice in use.

The flexible skirt may be formed of biological material, typically pericardial material.

The prosthesis is typically a mitral valve prosthesis.

There is still further disclosed herein a percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined above located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

There is further disclosed herein a method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined above in said catheter with said valve body in a collapsed state;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve with said skirt located toward the left ventricle; and

withdrawing said catheter from the patient.

Brief Description of the Drawings

Preferred forms of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

Figure 1 is a front elevation view of a percutaneous mitral valve prosthesis.

Figure 2 is a front elevation view of a sub-frame member of the valve body of the prosthesis of Figure 1.

Figure 3 is a schematic cross sectional front elevation view of the valve body of the prosthesis of Figure 1.

Figure 4 is a front elevation view of the valve body of the prosthesis of Figure 1 in a collapsed state located in a catheter.

Figure 5 is a front elevation view of an alternate valve body of a percutaneous mitral valve prosthesis.

Figure 6 is a front elevation view of the anchor device of the prosthesis of Figure 1.

Figure 7 is a plan view of the anchor device of Figure 6.

Figure 8 is a front elevation view of the anchor device of Figure 6 in a collapsed state located in a catheter.

Figure 9 is a schematic front elevation view of a patient depicting a guide wire accessing the patient's heart.

Figure 10 is a schematic cross-sectional front elevation view of a heart depicting a catheter advanced into the right atrium and a puncture formed in the inter-atrial septum.

Figure 11 is a cross-sectional front elevation view of the heart of Figure 10 with the catheter advanced into the left ventricle.

Figure 12 is a schematic cross-sectional front elevation view of the heart of Figure 10 with a percutaneous heart valve prosthesis advanced through the catheter.

Figure 13 is a schematic cross-sectional front elevation view of the heart of Figure 10 with the valve body of the prosthesis released from the catheter into the left ventricle.

Figure 14 is a front elevation view of the heart of Figure 10 with the catheter withdrawn into the right atrium and the prosthesis valve body located in the mitral valve orifice.

Figure 15 is a schematic cross-sectional elevation view of the heart of Figure 10 with the prosthesis fully deployed.

Figure 16 is a front elevation view of an alternative percutaneous heart valve prosthesis.

Figure 17 is a further view of the prosthesis of Figure 16.

Figure 18 is a front elevation view of the prosthesis of Figure 16 in a collapsed state located in a catheter.

Figure 19 is a schematic cross-sectional front elevation view of a heart with a partially deployed prosthesis of Figure 16.

Figure 20 is a schematic cross-sectional front elevation view of the heart of Figure 19 with the prosthesis fully deployed.

Detailed Description of the Preferred Embodiments

Referring specifically to Figure 1, a percutaneous heart valve prosthesis, in the form of a mitral valve prosthesis 1, comprises a valve body 2, first and second flexible valve elements 3, 4, an anchor device 5 and an anchor line 6 secured to and extending between the valve body 2 and the anchor device 5.

The valve body 2 has a first end 7 and a second end 8. A blood flow passage 9 extends along a longitudinal axis 10 between the valve body first end 7 and the valve body second end 8. The valve body 2 is configured so as to be collapsible about the longitudinal axis 10 to enable the valve body 2 to be located in a catheter for delivery of the prosthesis 1, as will be discussed further below.

The valve 2 is in the form of a collapsible valve body frame formed of elongate elastic valve body frame elements 11. Each of the valve body frame elements 11 may be suitably formed as wires of a superelastic shape memory material. A particularly suitable material is nitinol, a nickel-titanium alloy, which is known for use in percutaneous prosthesis applications. Other suitable elastic metallic materials include stainless steel, gold, other titanium alloys and cobalt chromium molybdenum. Other suitably rigid yet elastic metal alloys, or non-metallic materials, may also be utilized as desired. The valve body frame elements 11 will typically have a thickness of the order of 0.3 to 0.4 mm, however elements of varying diameter are also envisaged.

The valve body frame 2 depicted in Figure 1 comprises three valve body sub-frame members 12. One such valve body sub-frame member 12 is depicted in Figure 2. As can best be seen from Figure 2, each valve body sub-frame member 12 is in the general form

of a deltoid, and here particularly in the form of a diamond or rhombus (that is, a deltoid with four equal length sides). Each valve body sub-frame member 12 is arranged such that the acute-angled vertices 13, 14 of the rhombus are arranged at the valve body first and second ends 7, 8, with the oblique-angled vertices 15, 16 located between the valve body first and second ends 7, 8.

Each valve body sub-frame member 12 will generally be formed of two wires, kinked to form the oblique-angled vertices 15, 16, with the ends of each wire being soldered to form the acute-angled vertices 13, 14, thereby providing the rhombus form.

Alternatively, the wires could be kinked to form the acute-angled vertices 13, 14, with the ends soldered at the oblique-angled vertices 15, 16.

Adjacent valve body sub-frame members 12 are joined at their respective oblique-angled vertices 15, 16 as depicted in Figure 1, typically by soldering. Alternatively, the adjacent valve body sub-frame members may be sutured or joined by any other suitable means. Whilst, in the valve body 2 depicted, three sub-frame members 12 are joined so as to provide a generally triangular transverse cross-section, more than three sub-frame members may be utilised as desired such that the transverse cross-section of the valve body 2 becomes gradually more circular in shape with the addition of further body sub-frame members 12.

As is particularly apparent from Figure 1, the valve body 2 is arranged such that it tapers towards the valve body first end 7. The valve body is tapered and sized such that the valve body first end 7 is able to pass through a mitral valve orifice associated with a mitral valve to be replaced, with the valve body second end 8 being sized so as not to pass through such a mitral valve orifice, when in the uncollapsed state. A mitral valve orifice in an adult person typically has a diameter of the order of 25 mm.

Referring again particularly to Figure 2, each valve body sub-frame member 12 may further comprise a collapsible diagonal element 17 extending between the oblique-angled vertices 15, 16. The diagonal elements will typically be in the form of a kinked wire formed of the same material as the remaining elements 11 of the valve body sub-frame member 12. The kink is provided in the diagonal element 17 to enable it to readily collapse to allow delivery via catheter.

Referring to Figures 1 and 3, the valve elements 3, 4, in the form of valve leaflets, are secured to the valve body 2 on opposing sides of the bloodflow passage 9. Typically, the valve leaflets 3, 4 will be sutured to the diagonal elements 17 of the valve body sub-

sub-frame members 12. The valve leaflets 3, 4 are here overlapping, typically with a shorter leaflet 3 overlapped by a longer leaflet 4 lying between the shorter leaflet 3 and the valve body second end 8, such that, in use, the longer leaflet 4 lies on the outer or ventricular side of the valve body 2.

The valve leaflets 3, 4 are configured in a known manner so as to open toward the valve body second end 8, allowing bloodflow through the passage 9 in a direction from the valve body first end 7 toward the valve body second end 8, and to sealingly lock in response to pressure acting in the opposite direction, so as to block bloodflow through the passage 9 in the reverse or retrograde direction. The valve leaflets may be formed of biological material, such as pericardial material, as is well known in the art, or of any other suitable flexible valve materials known in the art, including woven metallic materials or non-metallic materials such as silicone. The valve leaflets may be sutured to the diagonal element 17 around the entire periphery of the passage 9, or may be hinged only at one or more discrete points around the periphery of the passage 9. Any of various well known valve leaflet configurations may be utilised so as to provide the one way valve function required, including configurations utilising one valve leaflet only or utilising three or more valve leaflets as is known in the art. Alternatively, a single valve element in the general form of a windsock might be utilised.

Referring to Figure 4, the configuration of the valve body 2 facilitates it being collapsed about the longitudinal axis 10, enabling it to fit within a catheter 18 for subsequent percutaneous deployment.

As depicted in Figures 1 and 2, prongs, typically in the form of barbs 19, may be spaced about the periphery of the valve body 2, typically at or adjacent the oblique-angled vertices 15, 16 of each sub-frame element, for engaging the native annular wall surrounding a valve orifice in use, as will be discussed below. Further barbs may be located at the acute-angled vertices 24 at the valve body second end 8. The barbs 19 will typically point toward the end 7, when the anchor line 6 is secured to the valve body first end 7.

Referring to Figure 5, a flexible skirt 20 may extend around the periphery of the valve body 2 for blocking retrograde bloodflow toward the valve body first end 7, between the valve body 2 and the native wall surrounding the mitral orifice in use. The flexible skirt 20 will typically be sutured to the diagonal element 17 of each valve body sub-frame member 12, and as such will effectively provide a continuation of the valve leaflets 3, 4 on the exterior of the valve body 2. The flexible skirt 20 may be formed of

biological material, such as pericardial material, or alternatively might be formed of any suitable flexible non-biologic material, such as, for example, silicone, polyester or dacron.

Referring to Figure 6, the anchor device 5 will also typically comprise a collapsible anchor frame formed of elongate anchor frame elements 21. The anchor frame elements 21 will again typically be formed of a superelastic shape memory material as per the valve body elements 11, and may again be formed of nitinol or other suitable elastic materials. Here the anchor device frame 5 is formed of an array of anchor sub-frame members 22. Each anchor sub-frame member has the general form of a rhombus. Rather than being joined side to side as per the valve body sub-frame members 12, however, the anchor sub-frame members 22 are here each joined in a radial pattern at their oblique-angled vertices 23, 24.

Accordingly, the anchor device 5 is collapsible from a stable substantially flat plate-like configuration (as depicted in Figures 6 and 7) to an unstable elongate configuration for location within a catheter 18 (as particularly depicted in Figure 8). The anchor device 5 is provided at one end, corresponding to the oblique-angled vertices 23, with a coupling 25 for releasably coupling to a guide element as will be discussed below. The coupling 25 may suitably be in the form of a threaded aperture.

The anchor line 6 will also generally be secured to the end of the anchor device 5 corresponding to the oblique-angled vertices 23, and will extend through the length of the anchor device 5 beyond the opposing oblique-angled vertices 24, such that tension applied to the anchor line 6 will tend to retain the anchor device 5 in the flat configuration. The anchor line 6 may be formed of any suitable flexible wire or cord, and may be suitably formed again of nitinol wire or stainless steel wire. Other suitable materials may include carbon fibre, polyimides or aromatic polyamides. Where elasticity in the anchor line is desired, other suitable materials may include polyether block amide (PEBAX), silicone or polyurethane.

The opposing end of the anchor line 6 will typically be secured to the valve body first end 7, typically by way of three further lines 6a converging from the acute angled-vertices 13 of each-frame member 12 of the valve body 2. Where desired, further anchor lines 6 extending between the valve body 2 and anchor device 5 may be utilised.

The structure of the valve body 1 and anchor device 5 may be covered with biological material or less thrombogenic material to reduce the possibility of blood clotting around the non-biological material from which the valve body 2 and anchor device 5 will typically be formed.

A surgical procedure for replacement of a native mitral valve 101 utilising the prosthesis 1 will now be described with reference to Figures 9 to 15. Given that the native mitral valve 101 and mitral valve orifice 102 will generally vary in size between patients, measurements of the native mitral valve 101 and orifice 102 may be made with the use of a compliant balloon and transthoracic and transesophageal echocardiography.

The compliant balloon is located in the valve orifice 102 and expanded so as to move the leaflets of the native valve 101 out of the way and enable measurement of the diameter of the mitral valve orifice 102. A measurement of the distance between the native mitral valve 101 and the region of the inter-atrial septum 103 is also taken.

Based on the measurements taken, a suitably sized prosthesis valve body 2 is selected to fit the size of the mitral valve orifice 102 such that the valve leaflets 3, 4, will be positioned in the vicinity of the native valve 101. The measurement of the distance between the native mitral valve 101 and the mid region of the inter-atrial septum 103 is also utilised to determine the length of the anchor line 6 extending between the valve body 2 and anchor device 5, such that the anchor line 6 will be taught when the prosthesis 1 is deployed, as will be discussed further below.

The venous system of the patient to be treated is accessed via a puncture 104, typically in the groin area, accessing the femoral vein 105. Access to the venous system might alternatively be made via other large peripheral veins such as the subclavian or jugular veins. The femoral vein 105 is, however, preferred given the compressibility of the femoral vein 105 once a catheter is removed from the patient to achieve haemostasis.

A guide wire 26, typically having a diameter of approximately 0.85 to 1.7 mm, is then inserted through the puncture 104 and along the femoral vein 105 and via the inferior venacava 106 to the right atrium 107 of the patient's heart 100 as depicted in Figure 9. If additional steadying of the guide wire 26 is desired, a snare may be introduced to the heart 100 through an arterial approach from the left or right femoral artery, aorta and aortic valve. The snare will then engage a J-tip on the end of the guide wire 26 and draw the end of the guide wire 26 through the arterial system to the exterior of the patient so that opposing ends of the guide wire 26 may be steadied.

A catheter 18, typically having an internal diameter of at least 8 French (approximately 2.8 mm) is then advanced over the guide wire 26 and into the right atrium 107. Referring to Figure 10, a puncture 108 is then made in the inter-atrial septum 103 using conventional equipment advanced via the catheter 18 in the known manner. The guide wire 26 and catheter 18 are then further advanced through the septal puncture 108

into the left atrium 109, through the native mitral valve 101 and into the left ventricle 110 as shown in Figure 11. The first end 27 of the catheter 18 is thus located in the left ventricle 110 whilst the opposing second end of the catheter 18 is still located on the exterior of the patient.

The mitral valve prosthesis 1 is then collapsed and fed into the second end of the catheter 18, with the second end 8 of the collapsed valve body 2 leading. An elongate prosthesis guide element 29 is detachably attached to the prosthesis 1, here by way of the screw threaded coupling 25 of the anchor device 5. The prosthesis guide element 29 may be a further guide wire with a cooperating screw threaded coupling 30 on its end, or alternatively might be a narrower catheter. The prosthesis 1 is advanced along the catheter 18 toward the catheter first end 27 as shown in Figure 12. Rather than using a screw threaded coupling arrangement 25, 30 to couple the anchor device 25 and prosthesis guide element 29, a clip, clamp or the like may be utilised.

The prosthesis 1 is advanced until the valve body 1 is released past the catheter first end 27 and into the left ventricle 110 as shown in Figure 13. As the valve body 2 is released from the catheter first end 27, the elasticity of the valve body frame results in the valve body 2 extending to its uncollapsed state. The valve body 2 remains attached to the anchor device 5 by way of the anchor line 6.

Referring to Figure 14, the catheter 18 is then withdrawn through the puncture 108 such that the catheter first end 27 is located in the right atrium 107. Simultaneously, the prosthesis guide element 29 is withdrawn so as to draw the expanded valve body 2 toward the native mitral valve orifice 102 and left atrium 109. As the valve body first end 7 is sized to enable it to pass through the mitral valve orifice 102, and the valve body 2 is tapered such that the valve body second end 8 is sized so as not to pass through the mitral valve orifice 102, the valve body 2 engages the annular wall 111 of the mitral valve orifice and thus becomes wedged within the valve orifice 102. The valve body diagonal elements 17 and valve leaflets 3, 4 are ideally positioned adjacent the native mitral valve 101, whose leaflets are pushed away and crushed against the mitral valve orifice wall 111 by the valve body 2. Accordingly, with the native mitral valve 101 being pushed away from the mitral valve orifice 102, there is no need to remove the native mitral valve 101.

The barbs 19 protruding from the valve body 2 and facing towards the valve body first end 7 (and thus the left atrium 109) pierce into the valve orifice wall 111 as the valve body 2 is wedged into position. The barbs 19 located adjacent the valve leaflets 3, 4 engage the valve orifice wall 111 in the vicinity of the native valve leaflets, whilst the

barbs 19 at the valve body second end 8 engage additional cardiac structure surrounding the lower end of the valve orifice 102 within the left ventricle 110.

The peripheral skirt 20 extending about the valve body 2 is located on the ventricular side of the mitral valve orifice 102, so as to seal between the periphery of the valve body 2 and the mitral valve orifice wall 111 when the left ventricle 110 contracts and pressurises during ventricular systole.

The catheter 18 is then further retracted such that the anchor device 5 is released from the catheter first end 27. As the anchor device 5 is released it expands to its un-collapsed state and, with appropriate sizing of the anchor line 6, engages the inter-atrial septum 103 from within the right atrium 107, as shown in Figure 15. The catheter 18 and guide wire 26 are then drawn back through the venous system and removed from the patient to complete the procedure. At any stage during the deployment process, the anchor device 5 and valve body 2 may be retracted back into the catheter 18 and removed if any difficulties are encountered.

The anchor device 5 thus securely anchors the valve body 2 in the mitral valve orifice 102 against migration towards the left ventricle 110 during atrial systole, when the left atrium 109 contracts and pressurizes. The tapered configuration of the valve body 2, effectively wedging the valve body 2 into the mitral valve orifice 102, anchors the valve body 2 against migration towards the left atrium 109 during ventricular systole. The barbs 19 additionally anchor the valve body 2 against migration towards the left atrium 109.

Once the prosthesis is successfully in place, the prosthesis guide element 29 is detached from the anchor device 5, by rotating the prosthesis guide element 29 to thereby decouple the threaded coupling.

The entire procedure may be performed under the guidance of fluoroscopy, transthoracic and transesophageal echocardiography in a known manner.

The valve leaflets 3, 4 replace the function of the native mitral valve leaflets, allowing bloodflow from the left atrium 109 to the left ventricle 110 through the mitral valve orifice 102 and bloodflow passage 9 of the valve body 2 during atrial systole, whilst blocking retrograde flow from the left ventricle 110 to the left atrium 109 during ventricular systole. The peripheral skirt 20 further blocks bloodflow through any gaps between the valve body 2 and the mitral valve orifice wall 111 in the retrograde direction during ventricular systole.

In addition to, or in place of, the barbs 19 and tapered shape of the valve body 2 anchoring the valve body 2 against migration towards the left atrium 109, a further anchor device 5 might be utilised to anchor the valve body 2 to the inter-ventricular septum 112. Similarly, the tapered form of the valve body 2 might be utilised in conjunction with other mechanisms for securing the valve body 2 against migration towards the left ventricle rather than utilising the anchor device. It is further envisaged that the general valve prosthesis configuration may be utilised for other types of heart valve prosthesis, for replacement of the aortic semiluminar valve, pulmonary semiluminar valve or tricuspid valve, utilizing alternative structures of the heart for securing the anchor device.

An alternate form of valve prosthesis 201 is depicted in Figures 16 to 20. The prosthesis 201 has an anchor device 5 much the same as that of the prosthesis 1 of Figure 1, however the valve body 202 is in the general form of a collapsible cylindrical ring. The collapsible ring 202 is formed of a squat cylinder and may have a woven construction formed of elongate elastic elements, typically metallic wire. Again, a particularly suitable material is a superelastic shape memory material such as nitinol. The valve body ring 202 should be sized so as to have an undeformed diameter slightly larger than that of the mitral valve orifice 102, such that when deployed, a compressive force is applied to the wall 111 of the valve orifice 102 to assist retaining the valve body in place. Care should be taken, however, not to oversize the valve body ring 202 such that an excessive compressive force is applied to the mitral valve orifice wall 111 which, as discussed above, may result in collapsing of the aortic outflow tract.

The valve body ring 202 is arranged such that it may be collapsed into a cylindrical shape of reduced diameter, enabling it to be loaded into a catheter 18, as depicted in Figure 18 in a similar manner to the valve body 2 described above.

Valve leaflets 3, 4, as described above in relation to the first prosthesis 1, are secured to the valve body ring 202, again typically by suturing. Here three anchor lines 6 secure the valve body ring 202 to the anchoring device 5, with the anchor line 6 being secured at points spaced equidistantly about the valve body ring 202.

Prongs 19 protrude from the valve body ring 202 toward the anchoring device 5 for engaging the valve orifice wall 111 in much the same manner as discussed above.

Referring to Figures 19 and 20, deployment of the prosthesis 201 is generally the same as that described above in relation to the first prosthesis 1, with the primary difference being the lack of a tapered body that is wedged into the mitral valve orifice 102 to assist anchoring against migration towards the left atrium 109. The valve body ring

202 thus relies on the barbs 19 and compressive force applied to the mitral valve orifice wall 111 to prevent migration towards the left atrium 109.

CLAIMS:

1. A percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

an anchor device, said anchor device being collapsible for delivery via catheter; and

an anchor line secured to and extending between said valve body and said anchor device.

2. The prosthesis of claim 1 wherein said anchor device comprises a collapsible anchor frame formed of elongate elastic anchor frame elements.

3. The prosthesis of claim 2 wherein said anchor frame is collapsible from a stable substantially flat disc-like configuration to an unstable elongate configuration for location within a catheter.

4. The prosthesis of claim 2 wherein said anchor frame elements are each formed of a superelastic shape memory material.

5. The prosthesis of claim 1 wherein said valve body comprises a collapsible valve body frame formed of elongate elastic valve body elements.

6. The prosthesis of claim 5 wherein said valve body frame elements are each formed of a superelastic shape memory material.

7. The prosthesis of claim 1 wherein said valve body tapers toward said valve body first end.

8. The prosthesis of claim 7 wherein said anchor line is secured to said valve body first end.

9. The prosthesis of claim 5 wherein said valve body frame comprises at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and oblique-angled vertices located between said valve body first and second ends.

10. The prosthesis of claim 9 wherein each said valve body sub-frame member has the general form of a rhombus.

11. The prosthesis of claim 9 wherein adjacent said valve body sub-frame members are joined at respective said oblique-angled vertices.

12. The prosthesis of claim 11 wherein each said sub-frame member further comprises a collapsible diagonal element extending between said oblique-angled vertices.

13. The prosthesis of claim 12 wherein said one or more valve elements is/are secured to said diagonal elements.

14. The prosthesis of claim 5 wherein said valve body frame is in the general form of a collapsible cylindrical ring.

15. The prosthesis of claim 1 wherein said prosthesis further comprises a plurality of prongs spaced about a periphery of said valve body for engaging the native wall of a valve orifice in use.

16. The prosthesis of claim 1 wherein said prosthesis further comprises a flexible skirt extending about a periphery of said valve body for blocking blood flow in said one direction between said valve body and the native wall of a valve orifice in use.

17. The prosthesis of claim 16 wherein said flexible skirt is formed of biological material.

18. The prosthesis of claim 17 wherein said flexible skirt is formed of pericardial material.

19. The prosthesis of claim 1 wherein said prosthesis is a mitral valve prosthesis.

20. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 1 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end, said anchor device being in a collapsed state and located between said valve body and said catheter second end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said anchor device and said guide element second end extending beyond said catheter second end.

21. A percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said valve body second end, said valve being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage;

wherein said valve body tapers toward said valve body first end, said valve body first end being sized to pass through a valve annulus associated with a heart valve to be replaced, said valve body second end being sized so as not to pass through the valve orifice.

22. The prosthesis of claim 21 wherein said valve body comprises a collapsible valve body frame formed of elongate elastic valve body elements.

23. The prosthesis of claim 22 wherein said valve body frame elements are each formed of a superelastic shape memory material.

24. The prosthesis of claim 22 wherein said valve body frame comprises at least three valve body sub-frame members, each said valve body sub-frame member having the general form of a deltoid, each said deltoid having acute-angled vertices at said valve body first and second ends, and oblique-angled vertices located between said valve body first and second ends.

25. The prosthesis of claim 24 wherein each said valve body sub-frame member has the general form of a rhombus.

26. The prosthesis of claim 24 wherein adjacent said valve body sub-frame members are joined at respective said oblique-angled vertices.

27. The prosthesis of claim 26 wherein each said sub-frame member further comprises a collapsible diagonal element extending between said oblique-angled vertices.

28. The prosthesis of claim 27 wherein said one or more valve elements is/are secured to said diagonal elements.

29. The prosthesis of claim 21 wherein said prosthesis is a mitral valve prosthesis.

30. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 21 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

31. A percutaneous heart valve prosthesis comprising:

a valve body having a valve body first end, a valve body second end and a passage extending along a longitudinal axis between said valve body first end and said

valve body second end, said valve body being collapsible about said longitudinal axis for delivery via catheter;

one or more flexible valve elements secured to said valve body and extending across said passage for blocking bloodflow in one direction through said passage; and

a flexible skirt extending about a periphery of said valve body for blocking bloodflow in said one direction between said valve body and the native wall of a valve orifice in use.

32. The prosthesis of claim 31 wherein said flexible skirt is formed of biological material.

33. The prosthesis of claim 32 wherein said flexible skirt is formed of pericardial material.

34. The prosthesis of claim 31 wherein said prosthesis is a mitral valve prosthesis.

35. A percutaneous heart valve replacement system comprising:

a catheter having a catheter first end and a catheter second end;

a prosthesis as defined in claim 31 located in said catheter, said valve body being in a collapsed state and located towards said catheter first end; and

an elongate guide element having a guide element first end and a guide element second end, said guide element first end being detachably attached to said prosthesis and said guide element second end extending beyond said catheter second end.

36. A method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 1 in said catheter with said valve body and said anchor device in a collapsed state, said valve body being located between said anchor device and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve;

withdrawing said catheter first end through said puncture and into the right atrium;

advancing said anchor device through said catheter until said anchor device is released from said catheter first end, thereby expanding said anchor device from said collapsed state;

engaging said anchor device with said inter-atrial septum about said puncture; and

withdrawing said catheter from the patient.

37. A method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 21 in said catheter with said valve body in a collapsed state and said valve body second end located between said valve body first end and said catheter first end;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, wedging said valve body in the orifice of the native mitral valve; and

withdrawing said catheter from the patient.

38. A method of treating a failed or failing mitral valve comprising the steps of:

advancing a first end of a catheter through the venous system of a patient to be treated into the right atrium of the patient's heart;

creating a puncture in the inter-atrial septum of the heart;

advancing said catheter first end through said puncture, into the left atrium, through the native mitral valve and into the left ventricle of the heart;

locating a prosthesis as defined in claim 31 in said catheter with said valve body in a collapsed state;

advancing said prosthesis through said catheter until said valve body is released from said catheter first end, thereby expanding said valve body from said collapsed state;

withdrawing said catheter first end through the mitral valve into the left atrium;

withdrawing said valve body toward the left atrium, locating said valve body in the orifice of the native mitral valve with said skirt located toward the left ventricle; and

withdrawing said catheter from the patient.

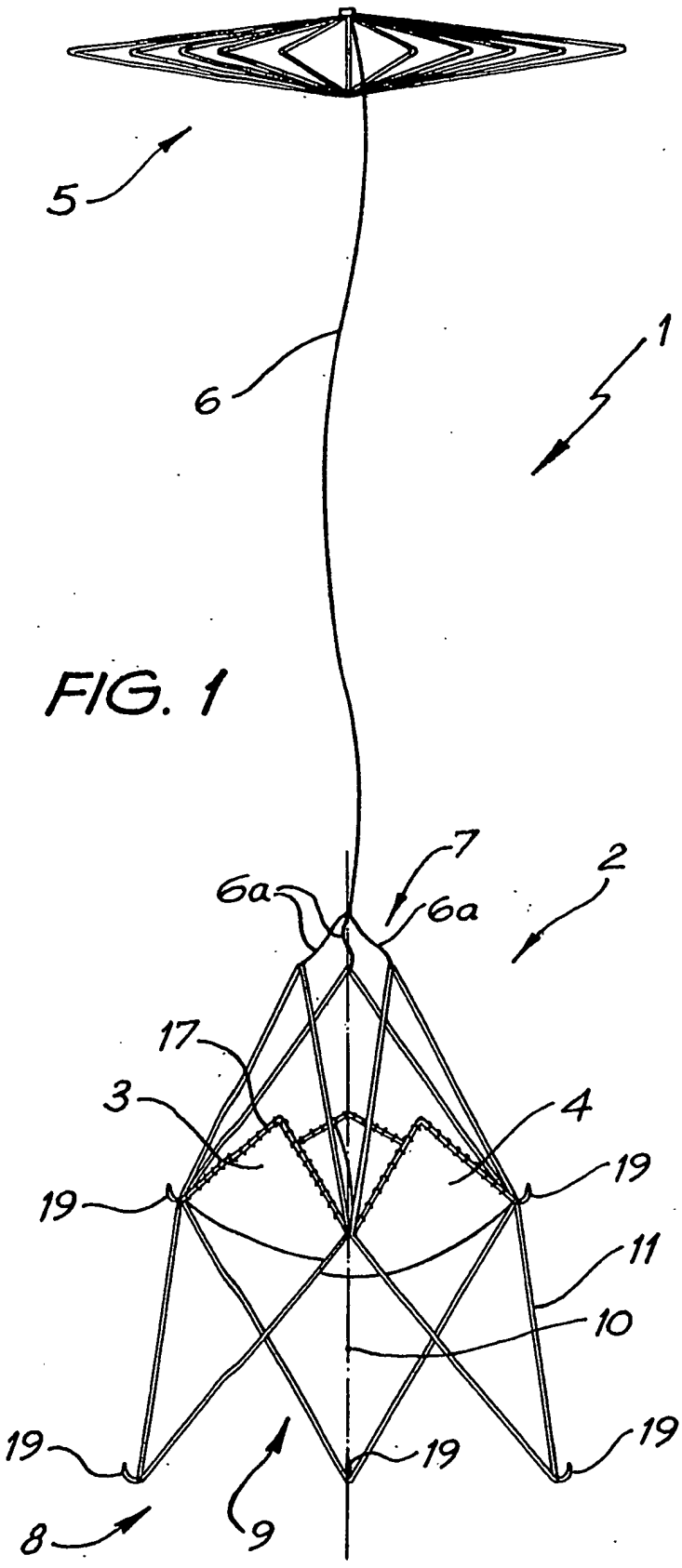


FIG. 1

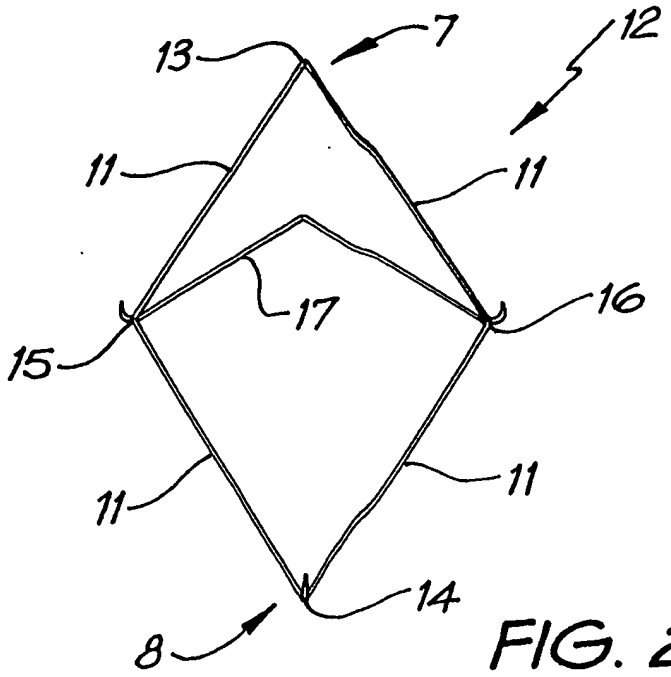


FIG. 2

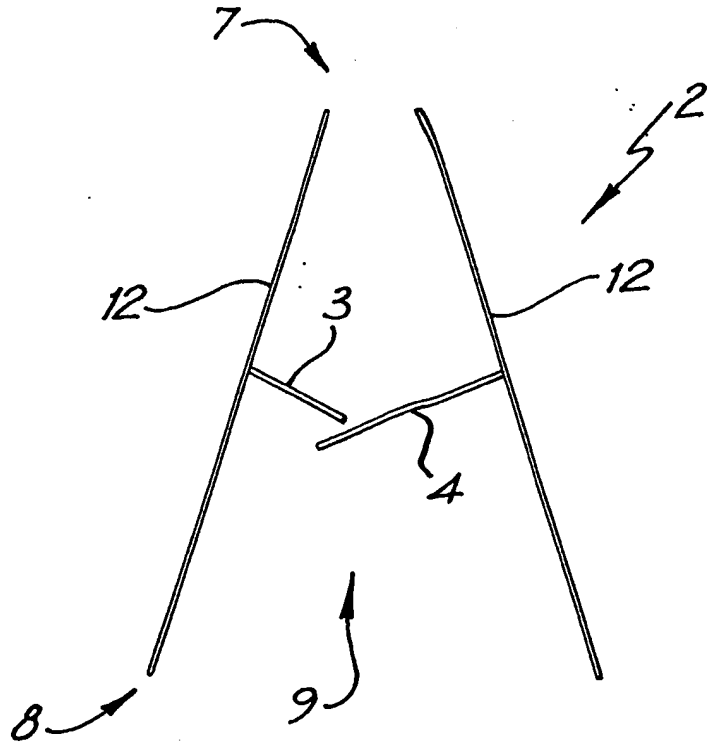


FIG. 3

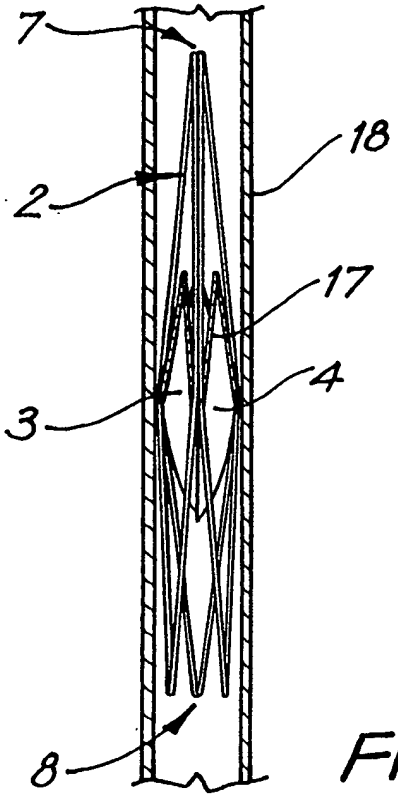


FIG. 4

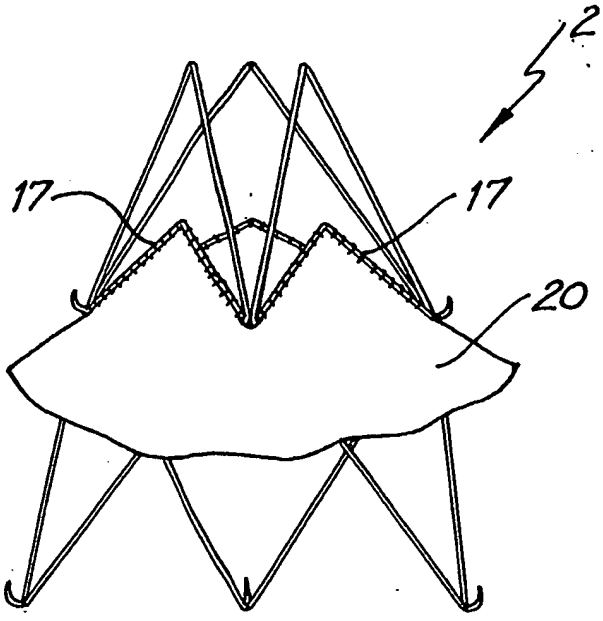


FIG. 5

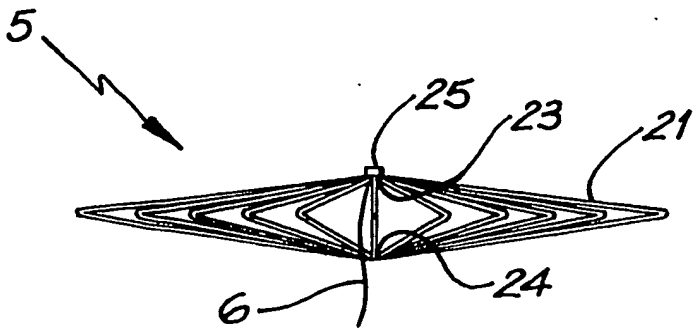


FIG. 6

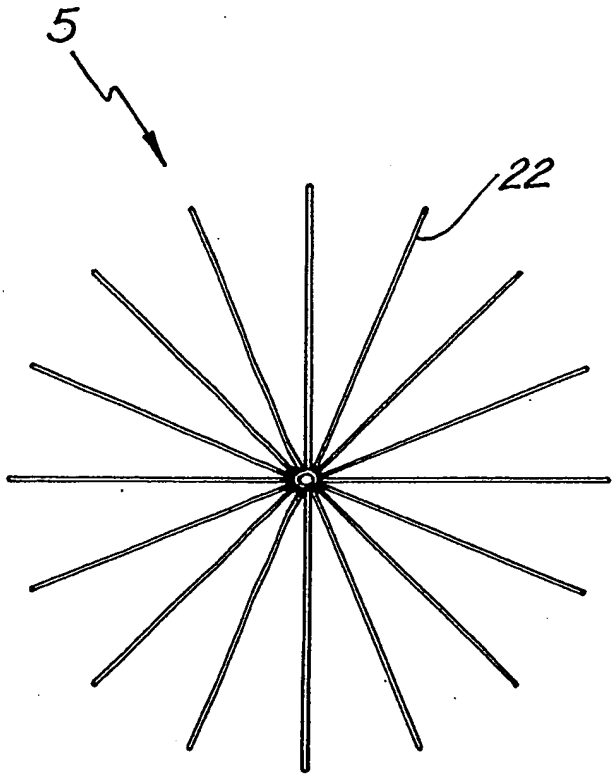


FIG. 7

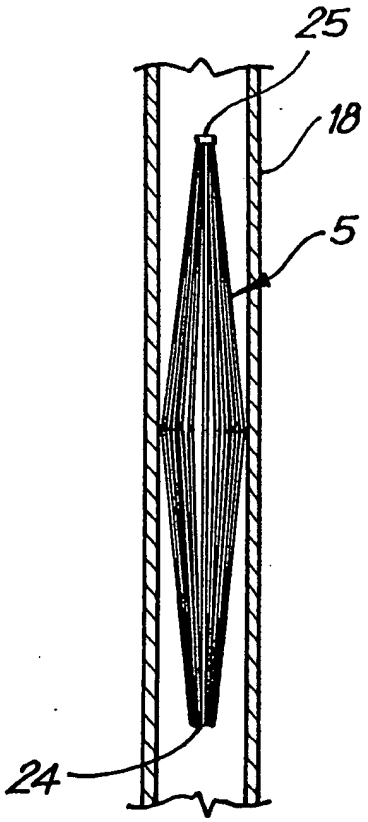


FIG. 8

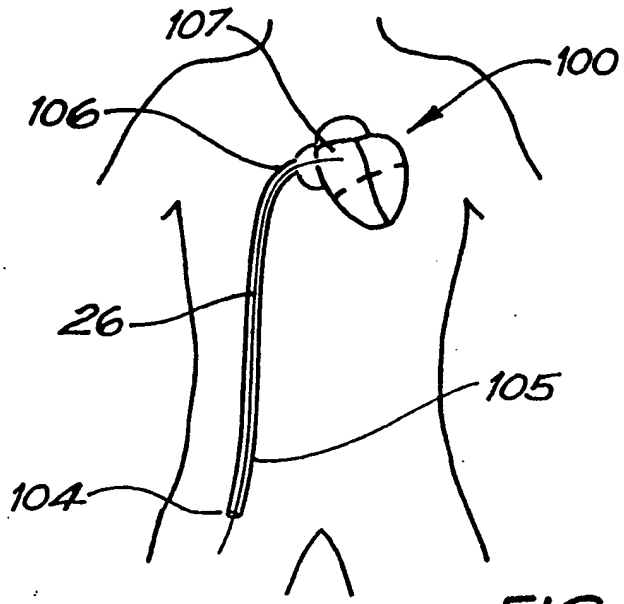
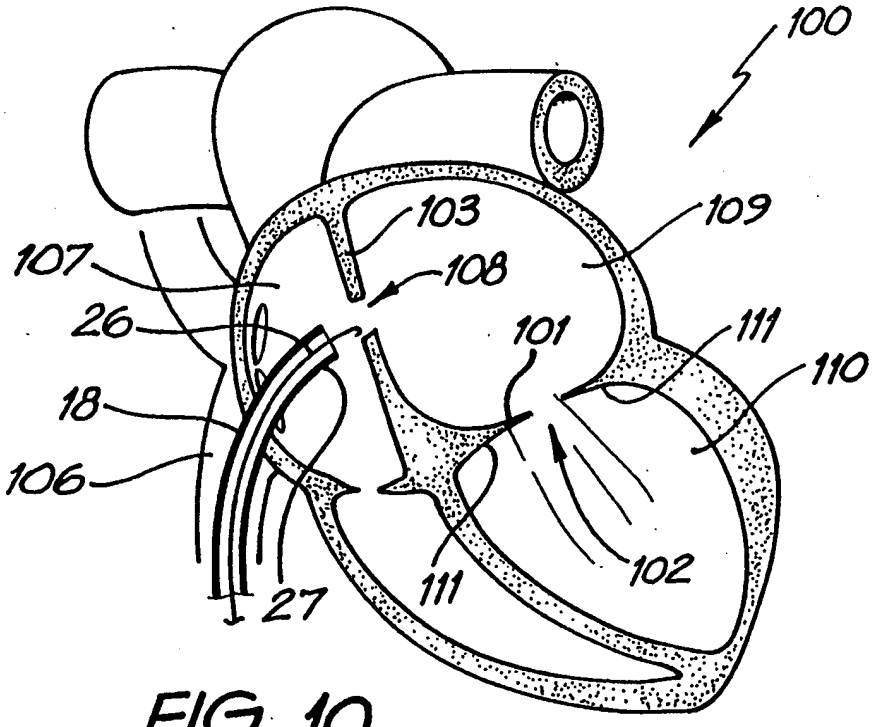

107
100
106
26
105
104

FIG. 9


100
103
109
107
108
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101
111
110
18
106
102
111
27

FIG. 10

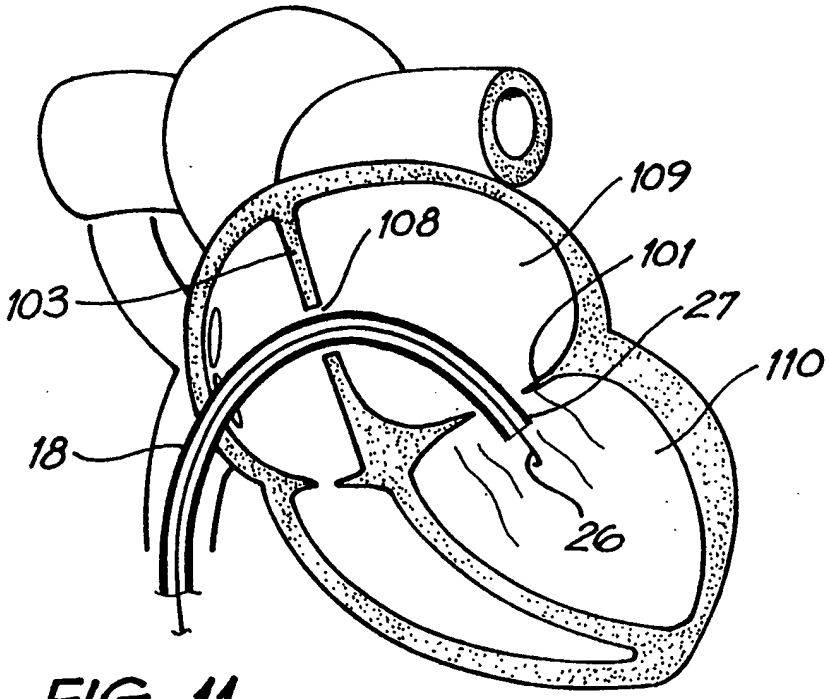

FIG. 11

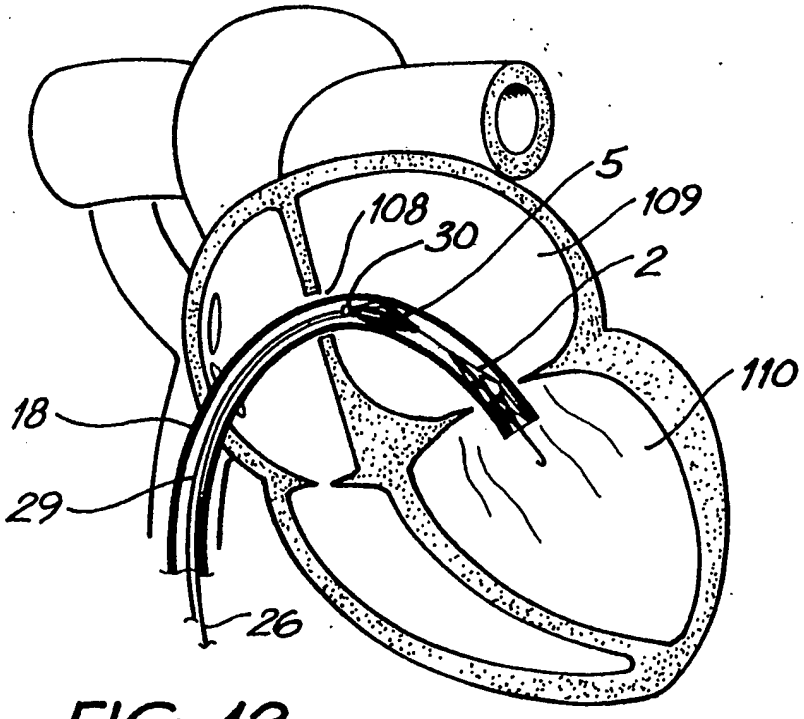

FIG. 12

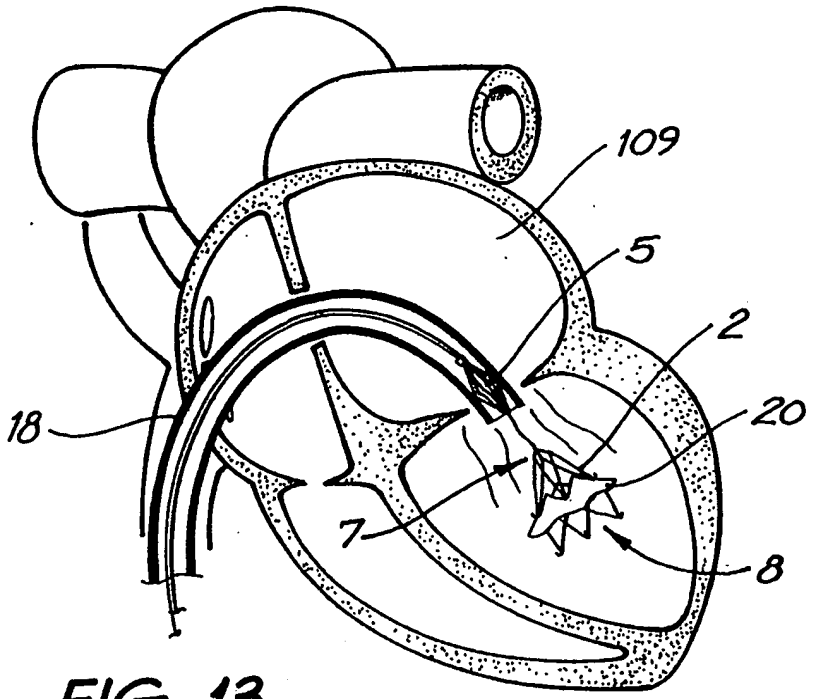

FIG. 13

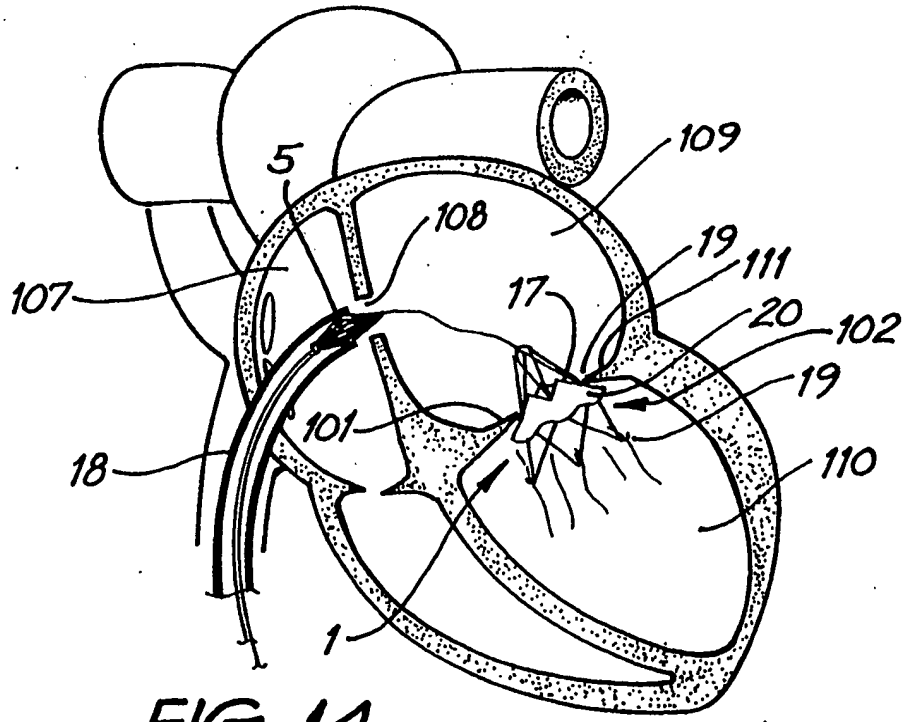

FIG. 14

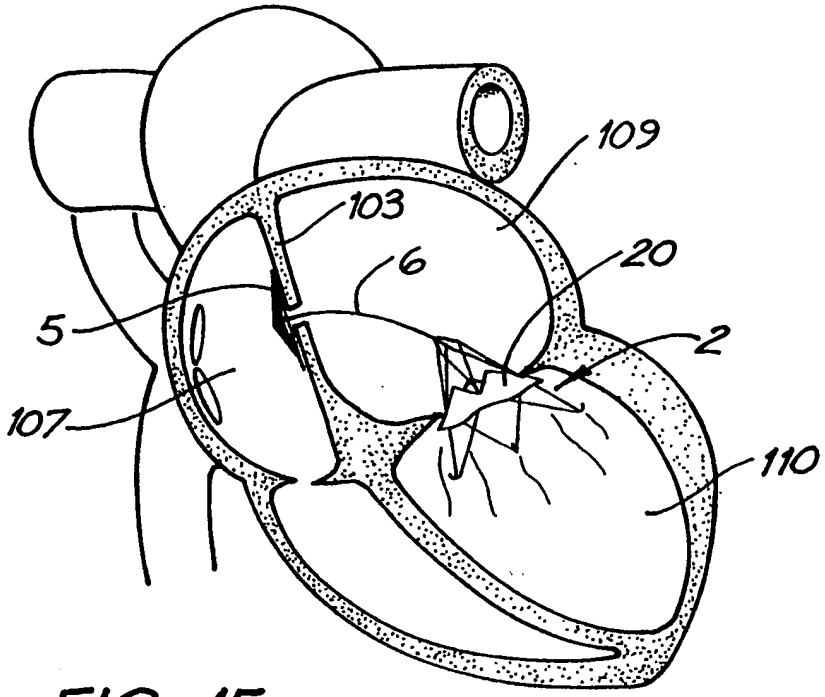

FIG. 15

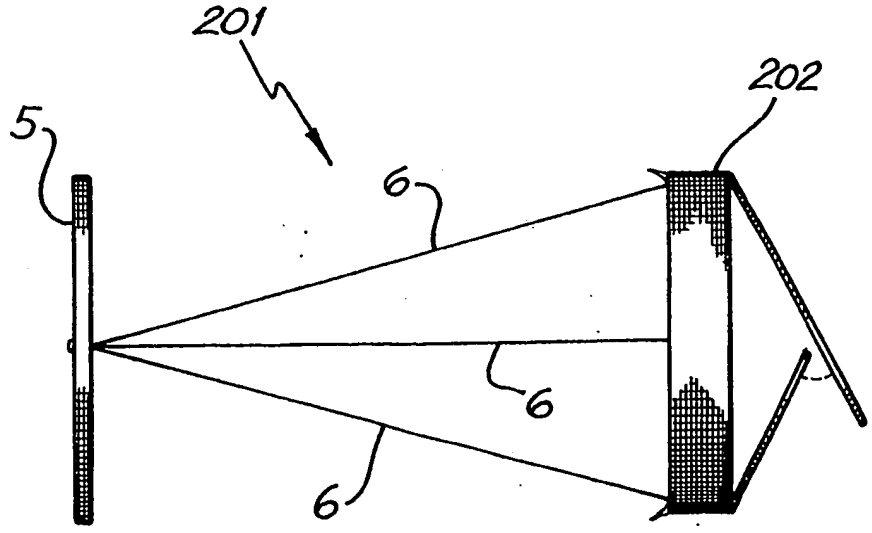

FIG. 16

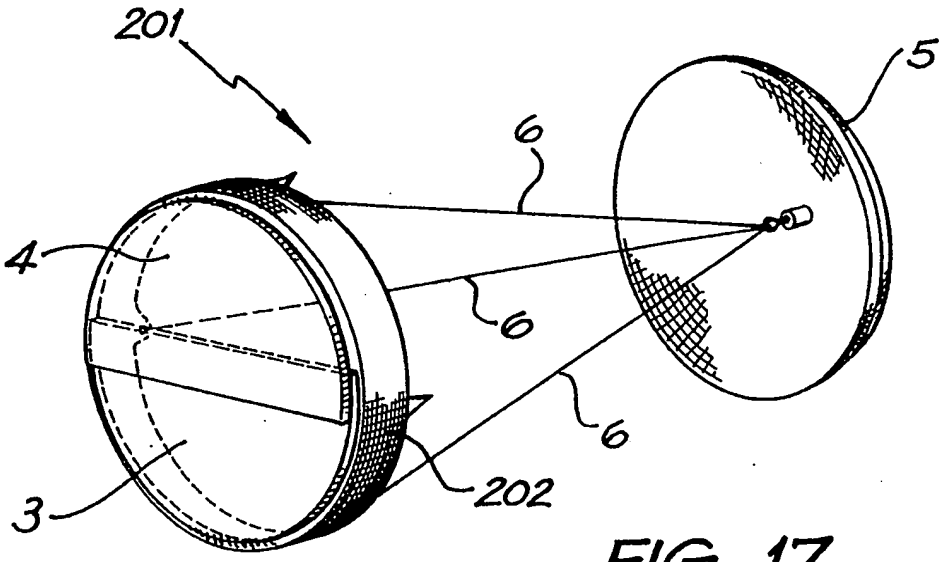

FIG. 17

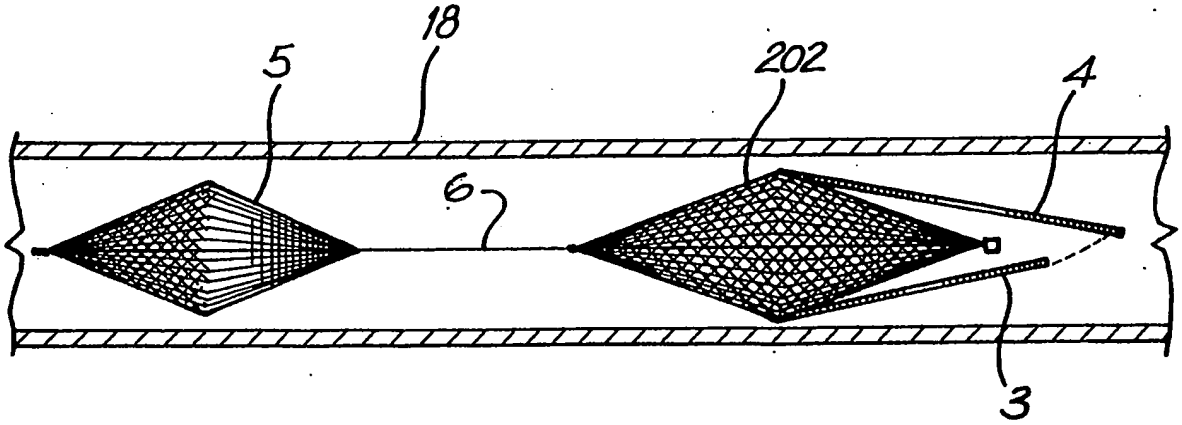

FIG. 18

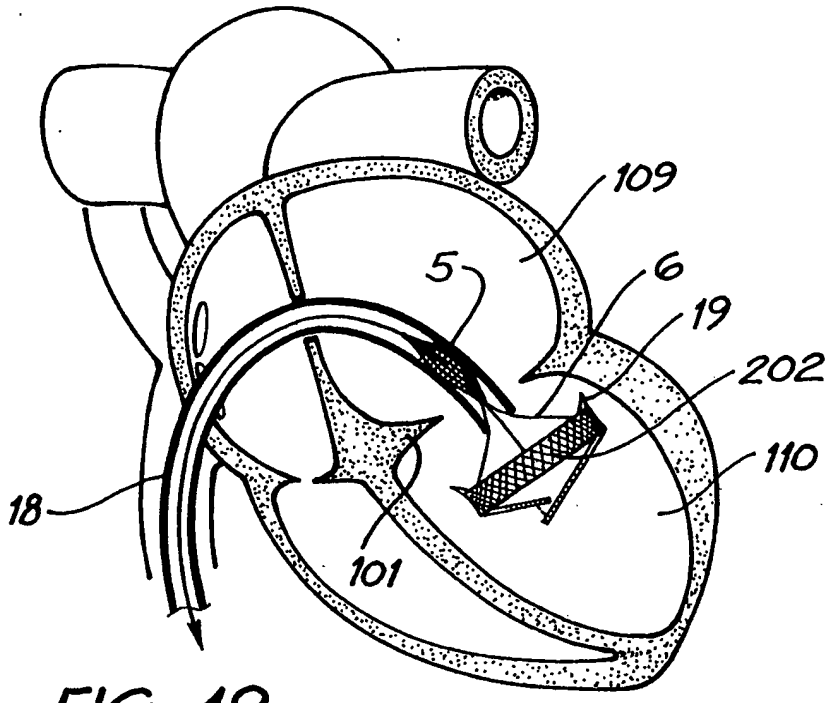

FIG. 19

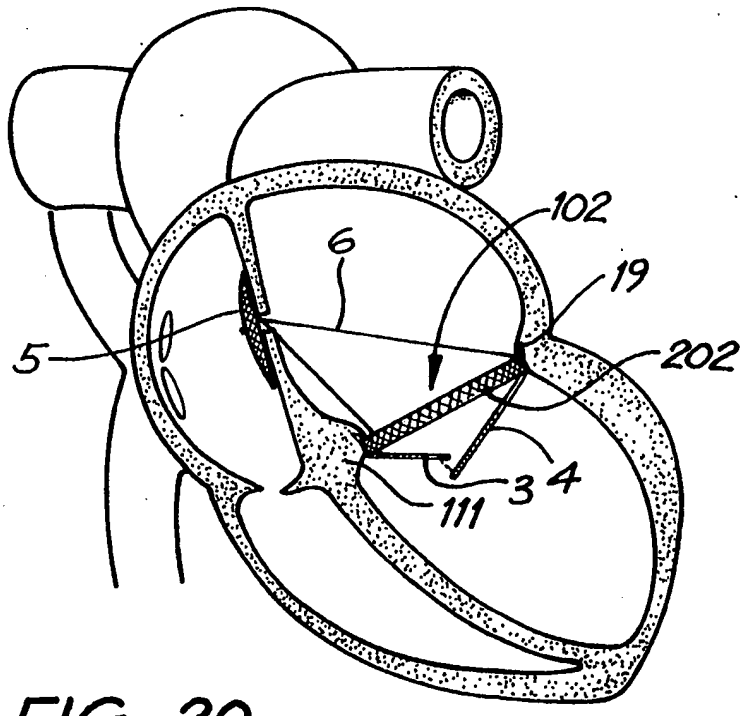

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000346

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61F 2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI IPC A61F, A61B, A61M +keywords: first invention: anchor, cable and similar terms; second invention: conical, taper and similar terms; third invention: skirt, gasket and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/003949 A2 (SEGUIN) 16 January 2003 Abstract and figure 1	1-11, 14, 15, 20-26, 30
X	US 6,458,153 B1 (BAILEY et al) 1 October 2002 Abstract and figures 6A and 6B	21-26, 29, 30, 37
A	US 6,332,893 B1 (MORTIER et al) 25 December 2001 Abstract	
A	US 2001/0018611 A1 (SOLEM et al) 30 August 2001 Abstract	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 2005	16 MAY 2005
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	XAVIER GISZ Telephone No : (02) 6283 2064

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000346

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2003/049648 A2 (CARDIAC DIMENSIONS, INC) 19 June 2003 Abstract	
A	US 6,616,684 B1 (VIDLUND et al) 9 September 2003 Abstract	
A	WO 2001/012105 A1 (CITRON LIMITED) 22 February 2001 Abstract	
A	US 6,358,277 B1 (DURAN) 19 March 2002 Abstract	
A	US 3,739,402 (COOLEY et al) 19 June 1973 Abstract	
A	EP 0 170 262 A2 (TERUMO CORPORATION) 5 February 1986 Abstract	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000346

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-20, 36 are directed to a percutaneous heart valve prosthesis comprising a collapsible valve body, an anchor device and an anchor line extending between valve body and anchor device. It is considered that an anchor line extending between valve body and anchor device comprises a first "special technical feature".

2. Claims 21-30, 37 are directed to a heart valve prosthesis comprising a collapsible valve body wherein valve body tapers such that one end passes through a valve annulus while the other end does not. It is considered that tapered valve body comprises a second special technical feature.

3. Claims 31-35, 38 are directed to a heart valve prosthesis comprising a collapsible valve body and a flexible skirt extending about a periphery of valve body for blocking blood flow in one direction between the valve body and wall of valve orifice. It is considered that a flexible skirt extending around the periphery of valve body comprises a third special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, *a priori*.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2005/000346

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
First invention claims 1-20, 36
Second invention claims 21-30, 37
Third invention claims 31-35, 38

See Extra sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2005/000346

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
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END OF ANNEX